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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,215	02/08/1999	BILL H. MCANALLEY	013258.0172	9780

27683 7590 11/10/2003

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/10/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/242,215

Applicant(s)

MCANALLEY ET AL.

Examiner

Michele C. Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,6-17,22,27-36 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,6-17,22,27-36 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed April 17, 2003. Further acknowledgment is made of the receipt and entry of the declarations under 37 CFR 1.132 filed by Dr. Stephen Boyd, Dr. Robert K. Murray, and Dr. Thomas H. Gardiner on April 17, 2003.

Claims 1, 6-17, 22, 27-36 and 40-43 are under examination.

Response to Amendment

Applicant's arguments have been fully considered but they are not persuasive for the reasons set forth in the previous Office action, and for the reasons set forth below.

Full consideration was given to the declarations of Dr. Stephen Boyd, Dr. Robert K. Murray, and Dr. Thomas H. Gardiner. Each of the declarations is directed to the idea that predigestion of the saccharides comprising the instantly claimed composition makes the saccharides bioavailable as monosaccharides. However, the declarations are not fully sufficient to overcome the rejections because the pending claims do not distinguish over the prior art as set forth in the previous Office action and for the reasons set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-17, 22, 27-36 and 40-43 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bounds of Claims 1, 22 and 40 are rendered uncertain by the phrase "wherein said composition comprises predigested forms of said saccharides" because it is unclear as to the degree of predigestion Applicant refers. Do the predigested forms of saccharides comprise saccharides obtained by removal of one monosaccharide moiety or more than one monosaccharide moiety? Or, are the predigested forms of saccharides of the claimed invention subjected to purification steps, including acid extraction or biological digestion, for example? The lack of clarity renders the claims ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 16 and 22 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by Linscott (A), and as evidenced by the teachings of Remington et al. (U). The rejection stands for the reasons set forth in the previous office action and set forth below.

Applicant claims a dietary supplement composition comprising nutritionally effective amounts of at least six saccharides, wherein at least one of said saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose, xylose and acetylated mannose; and wherein at least one of said saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid and arabinogalactan; and wherein said composition comprises predigested forms of saccharides.

Applicant argues that Linscott fails to teach the claimed invention because the supplemental fibers comprising the referenced granola bar are not predigested. However, Applicant's arguments are not persuasive because Linscott teaches a granola bar as a dietary supplement fiber, which comprises numerous ingredients including

apple pectin (galacturonic acid), gum arabic (arabinose, galactose, and glucuronic acid), gum ghatti (arabinose, galactose, mannose, xylose, and glucuronic acid), and guar gum (mannose and galactose), glucose, rice flour (glucose), and lecithin (see Column 2, lines 12-36 and claims).

Applicant further argues that while the fibers comprising the compositions taught by Linscott may include various constituent saccharides, the saccharides are not bioavailable as monosaccharides; and, in an attempt to support this position Applicant points to the declarations of Murray, Boyd and Gardiner. However, Applicant's arguments are not persuasive. For instance, as well pointed out by Applicant, the Office notes that on page 8, lines 19-23 of the present specification, Applicant discloses predigestion of the saccharides may be accomplished by one or more well known techniques such as:

"1) physical digestion such as shearing or treatment with ultrasound, 2) chemical digestion such as enzymatic digestion, and acid or base hydrolysis, and 3) biological digestion with microbes such as bacteria, fungi or molds."

The Office further notes that Linscott expressly teaches mixing the ingredients of her composition in a Hobart mixer, in Column 6, line 43 to Column 8, line 30; and that Linscott also teaches treating the compressed flakes of dietary fiber with a sonic sifter, in Column 8, lines 50-60. With particular regard to the arguments made by Dr. Murray, the Office respectfully disagrees that the dietary fibers comprising the Linscott' composition have not been pre-treated in some way to enable digestion and absorption of the sugars contained therein. As set forth immediately above, Linscott clearly

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teaches subjecting the dietary fibers of her composition to physical digestion. Furthermore, on page 155, Column 2, lines 23 to page 156, Column 1, lines 23, Remington teaches that rolled and flaky preparations of cereals (such as the compressed flakes of apple fiber, corn bran and rice flour; rolled oats; and crisped rice taught by Linscott) contain soluble saccharide. Like the method of rendering saccharides contained in cereals more soluble as taught by Remington, Linscott teaches a method of making her compressed flakes more soluble by mixing apple fiber, corn bran and rice flour with water, heating the mixture, extruding the mixture, grinding or particle sizing of the extrudate with a conventional shredder, and drying of the particles. As the dietary fibers of the composition taught by Linscott were subjected to physical digestion by extrusion, shearing and ultrasound, the saccharides comprising the dietary fibers of the composition taught by Linscott are deemed to inherently comprise predigested forms of saccharides. Moreover, as the composition taught by Linscott comprises rolled oats, crisped rice, chopped almonds, corn bran, etc., non-toxic vitamins and minerals are intrinsically inherent to the composition taught by Linscott.

The reference is deemed to anticipate the claimed subject matter.

Claims 1, 6 and 22 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by Bartolome et al. (V1), Kato et al. (W), and Beldman et al. (X). Newly applied as necessitated by amendment.

Bartolome teaches a dietary supplement composition comprising arabinose, xylose, mannose, galactose, glucose, and uronic acid obtained from a hemicellulose

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fraction extracted from the cell walls of pineapple fruit, on page 608, Column 1, lines 15-17. On page 610, Bartolome further teaches, "All fractions contained deoxyhexose (rhamnose or fucose) in trace amounts, xylose, arabinose, glucose, galactose, mannose, and uronic acid in different percentages (Table 1)." In Figure 1, Bartolome shows that the referenced extract was prepared from a freeze-dried extract of pineapple cell wall, which was treated with physical and chemical digestion, *i.e.*, ultrasound and hydrolysis with an acid or a base. Thus, the composition taught by Bartolome comprises predigested forms of saccharides.

Kato teaches a dietary supplement composition comprising a koji prepared from soybean hull with *Aspergillus* mold and hydrolyzed by cellulase of *Trichoderma*. Kato further teaches, "Rhamnose, xylose, arabinose, glucose, cellobiose, and dextrin were identified in a solution obtained by treating soybean hull koji with I [*Trichoderma* cellulase]"; and, "The soybean hull koji and wheat bran were mixed (1:1) and digested by I [*Trichoderma* cellulase]". As Kato teaches that the referenced composition comprises saccharides obtained from the cellulose of soybean hull by biological digestion with fungi, the composition taught by Kato comprises predigested forms of saccharides.

Beldman teaches a dietary supplement composition comprising a hydrolyzate of spent grain. Beldman teaches, "Spent grain is the residue of malt and grain which remains in the mash-kettle after the liquefied and saccharified starch has been removed by filtration. Chemical analysis of spent grain shows the presence of high amounts of polysaccharides (cellulose, hemicellulose (lignin)). Enzymic hydrolysis of spent grain by

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several commercial cellulases resulted in approximately 46% polysaccharide hydrolysis.

The hydrolyzate contained different monosaccharides: arabinose, xylose, mannose, galactose, glucose, rhamnose, and fucose."

Each of the cited references is deemed to anticipate the claimed subject matter.

Claims 1 and 6 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by Beran et al. (U1). Newly applied as necessitated by amendment.

Beran teaches a dietary supplement composition comprising an extract of potato mash saccharified with *Aspergillus niger* or with a combination of *Aspergillus niger* and *Aspergillus oryzae*, which contained fructose, galactose, glucose, maltose, maltotriose, isomaltose, panose, nonidentified pentoses, and galacturonic acid. As the composition taught by Beran comprises saccharides obtained from potato that was subjected to biological digestion with fungi, the composition taught by Beran comprises predigested forms of saccharides.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 7, 16 and 27-30 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Linscott (A) in view of Cayen et al. (B) and Pegel et al. (C). Newly applied as necessitated by amendment.

The teachings of Linscott are set forth above.

Linscott teaches the claimed invention except for dioscorea complex and beta sitosterol. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredients to the compositions taught by Linscott in the making of the claimed dietary supplement because Cayen teaches a composition comprising diosgenin (dioscorea complex) which is useful for lowering blood cholesterol and/or triglycerides, and which can be mixed with a beverage, for example water, milk or a fruit juice, or a food, for example, soups or a pulpy fruit; and, Pegel teaches medicaments, such as sitosterol- β -glucoside of diosgenin, having prostaglandin synthetase inhibitor activity which are used in the treatment of various diseases (see Column 4, lines 37-54; and Example 2). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of adding the dioscorea complex ingredient taught by Cayen and the dioscorea complex/sitosterol ingredient taught by Pegel to the composition taught by Linscott to provide the claimed dietary supplement because both

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Cayen and Pegel teach that their compositions as having beneficial health promoting activity.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above- cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 6-17 and 27-36 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Linscott (A), Cayen et al. (B) and Pegel et al. (C) in view of Graves (D), Balch et al. (V), Policappelli et al. (E), Morrison (F), and Dohnalek et al. (G). Newly applied as necessitated by amendment.

The combined teachings of Linscott, Cayen, and Pegel are set forth above. The combined teachings of Linscott, Cayen, and Pegel teach the claimed dietary supplement except for the numerous permutations of the instantly claimed ingredients, i.e., blend of freeze-dried and powdered raw fruits and vegetables; xanthines and herbal body-toning agents; melatonin; saccharide bioabsorption aid; and specified vitamins and minerals. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed ingredients to provide the claimed dietary supplement because Graves, Balch, Dohnalek, Policappelli, and Morrison teach the claimed ingredients as health-promoting agents. Firstly, Graves teaches a modified, edible pulp as a dietary supplement having hypochloesteric effect, which is made from dietary fiber. Sources of dietary fiber are selected from raw fruits such as apples, oranges, and grapefruit; and, raw vegetables such as carrots, corn, peas, and sugar beets; and grasses such as sugar cane; and grains such as barley and rice (see Column 6, lines 49-55). The modified pulp may be milled to form a flour or granulated for use as a table-top dietary supplement that is sprinkled onto various foods. The granulated table-top product may be combined with various herbs and spices. In Column 6, lines 53, Graves teaches that the major constituents of typical

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dietary fiber include cellulose, hemicellulose, lignin, and pectin. Graves further teaches that pectin comprises the saccharides galactose, arabinose, xylose, and fucose.

Secondly, Balch teaches that melatonin, vitamins, and minerals are essential to life and the maintenance of health. In particular, Balch teaches melatonin, selenium, vitamin A, vitamin C, vitamin E, beta-carotene, and zinc as antioxidants which protect the body from the formation of free radicals that can cause damage to cell, impairing the immune system, and leading to infections and various degenerative diseases. Moreover, Balch describes the disclosed vitamins and minerals as phytochemicals, which are biologically active substances found in fruits, vegetables, grains and legumes that appear to reduce the risk of cancer, heart disease, diabetes and high blood pressure. Balch specifically points to broccoli, brussel sprouts, cauliflower, cabbage, tomatoes and soybeans, as sources of plant materials containing health-benefiting phytochemicals, minerals, vitamins, and other nutrients. Furthermore, Dohnalek teaches a method of administering a therapeutic effective amount of powdered oligosaccharides, e.g., fructooligosaccharides (FOS), fructosans, xylooligosaccharides and galactooligosaccharides to humans for the reduction of diarrhea. In Column 2, lines 13-18, Dohnalek teaches that FOS occur in many plants, e.g., onions, garlic, asparagus, and tomatoes. Thirdly, Policappelli teaches herbal toning agents. For instance, Policappelli teaches a composition for dietary supplementation comprising herbal extracts combined with glucomannan or galactomannan, which is used for weight loss, weight control, and reduction of fats in the bodily organs. Finally, Morrison teaches a food supplement comprising a combination of ingredients including soya lecithin and

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mucopolysaccharides, etc. (see abstract and Column 3, lines 10-29). In Column 1, lines 51 to Column 2, lines 1-11, Morrison teaches that the combination of the ingredients in his dietary supplement have a proven synergy shown by improved health against coronary artery disease, cerebrovascular disease, and intermittent claudication. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the ingredients taught by Graves, Balch, Policappelli and Morrison to the dietary supplement composition taught by the combined teachings of Linscott, Cayen, and Pegel because Graves teaches his dietary supplement has enhanced hypocholesterolemic effect; Balch teaches the protective effects of the instantly claimed ingredients are found in plant materials and the claimed ingredients are often used in the making of multivitamin formulations, which can be sold as single dietary supplements; Dohnalek teaches that his oligosaccharides or fructooligosaccharides can be incorporated into the making of tablets, follow-on formula, toddler's beverages, yogurts, milks, fruit juice, and dietary supplements (see Column 3, lines 47-63); Policappelli teaches that his compositions reduce hunger, burn fat, and activate the body's metabolism without obligation to physical exercise (see Column 3, lines 50 to Column 4, lines 1-6); and Morrison teaches that lecithin has blood cholesterol lowering effect in patients with confirmed coronary heart disease (see Column 1, lines 48-50). This rejection is based on the well established proposition of patent law that no patentable invention resides in combining old ingredients of known characteristics where the results obtained thereby are no more

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than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett et al.*, 1266 USPQ 186.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

October 24, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER